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02/13/2002

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EXAMINER

BAUSCH, SARAE L

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/073,260 | Applicant(s) SIMMS ET AL. | |
| | Examiner SARAE BAUSCH | Art Unit 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 16-18, 21-25, 27-31, 55-57, 61-63 and 66-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 16-18, 21-25, 27-31, 55-57, 61-63, 66-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Currently, claims 1-11, 16-18, 21-25, 27-31, 55-57, 61-63 and 66-70 are pending in the instant application. Claim 12-15, 19-20, 26, 32-54, 58-60 and 64-65 have been canceled and claims 67-70 are new. This action is written in response to applicant's correspondence submitted 02/13/2002. All the amendments and arguments have been thoroughly reviewed but were found insufficient to place the instantly examined claims in condition for allowance. The following rejections are either newly presented, as necessitated by amendment, or are reiterated from the previous office action. Any rejections not reiterated in this action have been withdrawn as necessitated by applicant's amendments to the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is Final.**

Withdrawn Rejections

2. The rejections of claims 1-11, 16-18, 21-25, 27-31, 55-57, 61-63, and 66 under 35 U.S.C. 112, first paragraph, made in section 4, page 2 of the previous office action mailed 10/08/2007, is withdrawn in view of the amendment to the claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 112- New Matter

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 67-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Newly added claim 67 with the recitation “wherein said filter comprises two layers directly contacting one another” is not supported by the specification and raises the issue of new matter. The specification discloses two filter layers wherein the second filter is placed downstream of the first filter layer (see paragraph 43). The specification discloses a multilayer filter bed (see paragraph 41) as well as a filtration apparatus assembled by placing a second filter into a cartridge housing placing a first filter on top of the second filter and securing the first and second filter with an insert (see paragraph 46). However, the specification does not teach a first filter directly contacting a second filter nor does the specification define the term “directly”. The specification does not disclose if directly refers to a first filter in a straight line/direction with a second filter, a first filter immediately followed by a second filter, a first filter and a second filter with nothing in between the filters, or a first filter in communication with a second filter. The specification discloses a figure of the filtration apparatus, figure 8a-8b, however figure 8a depicts a first filter on top of a second filter but does not depict if the first filter is directly contacting the second filter in such a manner that would clearly disclose that the first filter is immediately followed by a second filter or if the first and second filters have nothing in between the filters. As the specification does not define the term “directly” the addition of the term “directly” changes the scope of the claims and the specification does not provide support for a first filter directly contacting a second filter.

Newly added claim 69 with the recitation of “second filter layer are about .2 μm in diameter” is not supported by the specification and raises the issue of new matter. The originally

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filed claims have support for a second filter layer that has a pore size of 1 to 500 μm , as well as 20 μm but the originally filed claims do not support the size of .2 μm for the second filter. The specification discloses that a multilayer filter bed has a pore size ranging from .1 μm to 500 μm however this does not disclose a second filter having a pore size of .2 μm (see para 41, page 14). The specification does teach a first filter that has a pore size of .2 μm (see para 44, page 15) but does not teach that the second filter has a pore size of .2 μm . The specification teaches that the second filter is from 1 μm to >300 μm and most preferably 10-70 μm and has an average pore size of 20 μm (see pg. 15 para 45) however this does not provide support for a second filter that has a pore size of .2 μm . The specification provides no indication of the criticality of the amended pore size and provides no examples of a second filter that uses the pore size of .2 μm . The subgenus of .2 μm pore size is not supported in the specification and raises the issue of new matter.

Response to Arguments

The response asserts on page 9 of the remarks mailed 02/19/2008 that support for the claim amendments and new claims can be found in the original claims, paragraph 62, and figure 8A. However the originally filed claims did not recite a first filter directly contacting a second filter. Furthermore, figure 8A does not depict a first filter directly contacting a second filter. Figure 8A depicts space between the first and second filter (see figure 8A) and thus figure 8a does not show that the first filter is directly contacting the second filter. Furthermore paragraph 42 of the published application, US 2002/0127587 A1 describes cell disrupting and cell lysis but does not describe a first filter directly contacting a second filter. Additionally paragraph 42 of the specification does not describe a first filter directly contacting a second filter. Thus

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specification does not provide support for the newly added claims 67-70 as there appears to be no support for a first filter directly contacting a second filter.

Maintained Rejection

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1-11, 16-18, 21-25, 27-31, 55-57, 61-63, and 66, are rejected under 35 U.S.C. 102(b) as being anticipated by Jones (PCT WO95/02049). Jones teaches a method of separating biological compounds from cells by filtration using two filters with increasing pore

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size in the direction of sample flow. This rejection was previously presented in section 12 of the office action mailed 12/19/2005 and is reiterated below.

With regard to claim 1, Jones (WO95/02049) teaches a method of purifying DNA (biological macromolecule) from *E. coli* bacterial culture (biological sample) by passing the cells through a 1 μ m filter followed by a 20 μ m filter (page 22, 1st full paragraph). Jones et al. teaches that the method can be used for genomic DNA (see page 4, 1st paragraph).

With regard to claim 2, Jones teaches the method of purifying nucleic acid from cells that comprises lysing a cell suspension to form a cell lysate containing nucleic acid and applying the cell lysate to a filter to remove unwanted cells and cell debris (page 2, 4th full paragraph).

With regard to claims 3-5, Jones teaches that any cell producing a target compound may be used in their invention. Jones defines a “cell” to encompass bacterial cells, cells from higher organisms for example blood cells, phage particles, and other cell types or organelles which contain the target compound and may require some form of lysis step to release it (page 3, 4th full paragraph). The cells are lysed prior to applying to the first filter (page 2, 4th full paragraph).

With regard to claims 6-11, Jones teaches that the target compound to be separated may comprise nucleic acid (instant claim 6), protein, or other desired compounds, in particular purifying recombinant proteins and antibodies (instant claim 7)(page 2, 2nd and 3rd paragraph). Jones further teaches that RNA or DNA may be purified using this invention (page 5, 2nd paragraph) (instant claim 8-11).

With regard to claims 16-18, Jones teaches the use of two filter layers to purify DNA from bacterial cells, with the first filter having 1 μ m pore size and the second filter having 20 μ m pore size (instant claims 16-18) (page 22, 1st full paragraph).

With regard to claims 21-25 and 27, Jones teaches the use of a first filter that retains unwanted cells and cell debris (instant claim 21), that is made of any material that can tolerate the reagents such as cellulose acetate (acetylated cellulose) (instant claim 24 and 25) and is no greater than 50 μm in pore size and no smaller than .2 μm (instant claim 22-23) (page 6, 1st full paragraph). Jones teaches that for a nucleic acid, the filter is typically glass or resin based and can bind the nucleic acid such as borosilicate glass (see page 6, 2nd paragraph) (claim 24). Jones teaches that the first filter is no greater than 50 μm in pore size and no smaller than .2 μm (see page 6, 1st paragraph) and the second filter is a 20 μm pore size (see page 22, 1st full paragraph) (instant claim 27).

With regard to claim 28 and 29, Jones teaches the method of a membrane filter that is placed inside the column (tube) (instant claim 29) and has a cylindrical shape (instant claim 28) (page 11, last paragraph, figure 1 and figure 2).

With regard to claims 30-31, Jones teaches the method of lysing a cell suspension to form a cell lysate, applying the cell lysate to a filter to remove unwanted cells and cell debris, contacting the filtered lysate with a solid phase matrix, separating the resultant filtered lysate from the matrix, and eluting the nucleic acid from the matrix (page 2, 4th full paragraph). Jones teaches the method of purifying plasmid DNA by using a filtration method of increasing pore sizes of two filters using a 1 μm filter followed by a 20 μm filter and promoting the flow of lysate through the filters by positive pressure (page 22, 1st full paragraph).

With regard to claim 55-57 and 61-63, Jones teaches the method of lysing a cell suspension from *E. coli* (natural source) to form a cell lysate, applying the cell lysate to a filter to remove unwanted cells and cell debris, followed by contacting the filtered lysate with a solid

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phase matrix, separating the resultant filtered lysate from the matrix, and eluting the nucleic acid from the matrix (page 2, 4th full paragraph). Jones teaches the method of purifying plasmid DNA (instant claim 57) by the method of increasing the pore sizes of the filters (instant claim 55), by using a 1 μ m cellulose acetate filter followed by a 20 μ m PTFE filter (instant claim 61-62) and promoting the flow of lysate through the filters by positive pressure (instant claim 56) (page 22, 1st full paragraph and Table 1, page 21). Jones teaches that for a nucleic acid, the filter is typically glass or resin based and can bind the nucleic acid such as borosilicate glass (see page 6, 2nd paragraph) (claim 63).

With regard to claim 66, Jones et al. teaches two filters that have the inherently property of shearing genomic DNA, as evidenced by applicant's own specification (see page 13, last paragraph to page 14, 1st line).

Response to Arguments

7. The response traverses the rejection on page 3 of the response mailed 02/19/2008. The response asserts that the claims are drawn to a filter with a biological sample and the filter comprises two filter layers wherein the filter comprises a first filter layer and a second filter layer that in contact with each other. The response asserts that Jones does not disclose a first filter layer that is in contact with a second filter layer as Jones discloses two filters separated by a conduit and a chamber. This response has been thoroughly reviewed but not found persuasive. It is noted that the claims do not require that the first filter is directly contacting the second filter. The claims merely require that the first filter is in contact with the second filter, which can encompass a first filter in communication with a second filter, via fluid or conduit as depicted in figure 5 of Jones. Additionally the term contact can encompass an association with and thus the

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biological sample that passes through the first filter and the second filter thus allows for the first and second filter in contact with each other via the association with the biological sample contacting both filters. Furthermore, the claim does not encompass direct contact of the filters with each other, thus the filters maybe indirectly contacted, as depicted in figure 5 of Jones, through fluid conduit and being housed in the same unit. Furthermore, the specification does not define the term “contact” and thus has been given its broadest reasonable intrepetation to encompass an association, communication, close interaction, a channel for communication between two groups and thus Jones et al. does teach a first filter that is in a direct line, communication, interaction to a second filter (see figure 5). The instant pending claims does not exclude additional elements, such as two filters separated by a conduit and chamber as taught by Jones et al. For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

8. Claims 67-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Nieuwkerk et al. (US Patent 5438128). This rejection is newly presented, necessitated by the amendment to the claims.

Nieuwkerk et al. teaches a method for convenient and rapid isolation of nucleic acids (see column 2 lines 64-68). Nieuwkirk et al. teaches a device for the isolation of nucleic acids that comprises stacked membranes that have a pore size of .1 to 12 microns and teaches that the preferred number of stacked membranes (first and second filter directly contacting) is from one to 20 (see column 2, lines 28-40). Thus, Nieuwkirk teaches a first and second filter in contact

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with each other with a first filter having a pore size of between .1 and 100 micron and a second filter having a pore size of .2 micron (claims 68-69). Nieuwkirk et al. teaches plasmid purification by contacting the filter with cell lysate (see example 1, column 8 lines 28-67) (claim 70).

Conclusion

9. No claims are allowable.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARA BAUSCH whose telephone number is (571)272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Sarae Bausch/
Primary Examiner
Art Unit 1634

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